In 2009, the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) released “Opioid Treatment Guidelines: Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain.” Three years later, Pain Medicine News asked some of the authors of the guidelines to revisit them.

PMN: In hindsight, what are your overall feelings about the guidelines? Do you feel they have made an impact clinically?

Gilbert J. Fanciullo, MD, director, Pain Management Center, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire: I do. They summarized what the thought leaders in the United States felt were the most important clinical issues related to opioids at the time. We used evidence-based medicine techniques to develop recommendations based on the evidence and the clinical opinions of these leaders. These guidelines served and continue to serve as the benchmark for all other opioid guidelines. The APS/AAPM guidelines were and still are the least biased of all opioid guidelines, and that is not simply a coincidence; it was intended by design. They remain as a snapshot of opinions of the leading experts in the field during a brief period in 2009. If you want to see what guidelines look like when done correctly, these guidelines can serve as that example.

Jeremy A. Adler, MS, PA-C, Pacific Pain Medicine Consultants: I am very proud of the work accomplished by the guidelines committee. The guidelines were developed to achieve multiple goals. The foundation was to provide recommendations for patient care that would be applicable in most clinical situations, and have these recommendations based on the best available scientific evidence. Where there were gaps in the evidence, consensus provided guidance for the missing information based on current best practices. A key component to the guidelines was identifying research gaps so researchers could be directed toward developing the much-needed evidence. Although most of the recommendations are based on consensus, I believe they have served an important purpose and have had marked positive clinical impact. The concept that opioids can be safe and effective in carefully selected and monitored patients is important and has been disseminated in a number of ways. Courses, workshops, and other education programs have been developed and have distributed this information to large audiences. The idea of providing opioids in the framework of a “trial” with goals and an exit strategy has been well received. Even a few years since publication, the guidelines remain relevant as greater awareness is brought to the balance between providing best practices for the management of pain and focusing on the issue of prescription drug abuse.

Steven Passik, PhD, professor of psychiatry, professor of anesthesiology, Vanderbilt University Medical Center, Nashville, Tennessee, and Pain Medicine News Editorial Board member: I think that the guidelines have been important insofar as they...
represent legitimacy of the practice of opioid therapy at a time when the opioid pendulum has been swinging back toward avoidance again. It codifies aspects of good practice (although it didn’t go far enough in some respects) and brings together the evidence, which, more than anything, demonstrated how far we need to go in terms of getting more evidence.

Jane C. Ballantyne, MD, professor of education and research, Department of Anesthesiology and Pain Medicine, University of Washington School of Medicine, Seattle: I think they have encouraged prescribing. I think they have been used to justify continued prescribing of opiates for chronic pain.

David Fishbain, MD, professor (tenured) of psychiatry and behavioral sciences, adjunct professor, Department of Neurological Surgery, adjunct professor, Department of Anesthesiology, Leonard M. Miller School of Medicine, University of Miami, Miami, Florida, and Pain Medicine News Editorial Board member: I believe they have made very little clinical impact.

Perry G. Fine, MD, professor, Department of Anesthesiology, University of Utah School of Medicine, Salt Lake City: In the absence of a formal evaluative process, it is not possible to say, one way or the other, what the impact on practice or clinical outcomes has been. However, feedback from the medical community has been almost universally positive and appreciative, and the guidelines have been cited broadly. They also have been used as a model for state-based guidelines. This leads me to believe that the effort to produce them was worthwhile, and at the very least, the guidelines have led many clinicians to think beyond their previously held knowledge base and practice patterns.

Roger Chou, MD, assistant professor of medicine, Division of General Internal Medicine, Oregon Health & Science University, Portland: I think the guidelines were one of the first real efforts to really critically look at the evidence on using opioids for chronic noncancer pain, and then provide actionable recommendations to clinicians, and tools to implement the recommendations in clinical practice. It’s pretty remarkable to bring together 20 or so experts from very different fields and have them reach consensus on the recommendations.

I think the guidelines have made some impacts—many of the principles in the guidelines have been adopted by state agencies and other groups trying to help clinicians making everyday decisions about opioids. The principles regarding risk assessment and the need to structure care (or to choose not to use opioids in some patients) to minimize risks are important ones that we continue to try to hammer home.

PMN: Is there anything you feel, looking back, that could have been addressed in the guidelines but was not?

Mr. Adler: For a publication that was intended to accomplish so many goals, I think the pertinent issues were addressed in full.

Dr. Fine: The very real challenge in creating the guidelines was the paucity of high-quality evidence available to inform practice recommendations. Regrettably, 3 years later, the literature has not miraculously become more robust, given the meager amount of research dollars available to address the most important questions, which have been framed in the publications that accompanied the release of the guidelines. What we do know is that there has been a parallel rise in prescription opioid-related morbidity and mortality with the increased use of opioids in the treatment of noncancer chronic pain. Clearly, principles of prescribing and practice need to be further defined and adhered to so that there is the optimal match of treatments to produce predictable, positive therapeutic outcomes and minimize harms. Evidence-based guidelines are important, but are only a piece of a more complex public health-oriented approach needed to address the complex medical and social issues involved in the management of chronic pain and its interface with opioid-related misuse.

Dr. Fanciullo: Not really.

Dr. Chou: I think the guidelines were pretty comprehensive; one of the criticisms is actually that it is “too much” for most clinicians to do. I would argue that given the unique safety issues, abuse potential, and societal harms associated with opioids, there really wasn’t anything that could be cut out.

Dr. Passik: I think the scope and prevention of the problem of opioid-related overdoses should have been more explicitly included.

Dr. Fishbain: No, I don’t think so; I think we addressed what we needed to.

Dr. Ballantyne: I think the issue of patient selection could have been better addressed. My own perspective is that not all patients are suitable candidates for opioid treatment, and that wasn’t really addressed in the guideline.
**PMN:** Are there any areas that you feel didn’t go far enough? Meaning, you addressed it, but perhaps could have worded the recommendations more strongly/differently?

**Dr. Ballantyne:** I think the issue of dependence and the fact that commitment to treatment often turns into a lifelong commitment wasn’t really addressed enough. In other words, once treatment has persisted for months or years, it is very hard to get people off of opioid treatment, even if it is not working very well. There wasn’t any guidance about decision points and when that discussion should be had.

**Dr. Passik:** I believe that various aspects of risk management practice have progressed beyond the guidelines because there was such a grave need; for example, the frequency and timing of urine drug screening was left vague. It has become commonplace and much more frequently used than was alluded to in the guidelines. This has been due, in part, to new data to support the practice, but more than anything to a developing community standard of care in response to the need to protect patients and practices against abuse, misuse, and diversion.

**Dr. Chou:** At the time, there wasn’t much evidence on incremental risks associated with higher doses, and recent studies suggest that risk starts to go up at really relatively low doses. So, the threshold for what is considered a “high dose” probably wouldn’t be the same now as it was even 2 or 3 years ago, when we had almost no data on differential risks.

Related to that, I think there is growing recognition that a substantial proportion of patients with chronic noncancer pain simply don’t respond to opioids—and that if these patients have not responded by the time they are at the equivalent of 60 or 80 mg per day of morphine, they probably aren’t going to respond at higher doses. Although we still don’t have a lot of “hard” data to support this, I think almost every clinician has seen this in clinical practice. The idea of “titrate up until you get a treatment response” is probably on its way out. In addition to the fact that some patients just don’t respond all that well to opioids, we know that on average we see a 20% to 30% reduction in pain scores. So, titrating until pain is gone—or nearly gone—just results in a lot of people on very high doses of opioids, who are probably no better off than if they were maintained at much lower doses.

**Dr. Fishbain:** Again, no, I think the guidelines were very precise and thorough; I wouldn’t change any of the wording.

**PMN:** What is the most common positive feedback you receive with regard to the guidelines? Do you hear any negative feedback?

**Dr. Chou:** Common positive feedback is that the guidelines help lay out expectations about risk assessment and monitoring and suggestions on how to structure opioid treatment and monitoring to match risk assessment. People like that tools are provided to aid with risk assessment and documentation, including

**Dr. Fine:** The guidelines voiced strong cautions and concerns with regard to indications, dose initiation, titration, monitoring, high-risk patients, concerns about methadone, and so on. My concern, looking back, and forward is that what was recommended has not been sufficiently embraced.

**Dr. Fanciullo:** My own bias was for more intensive monitoring of all opioid patients. I would have included urine toxicology testing as a recommendation for all opioid patients with chronic noncancer pain. That, however, was not the feeling of the group and the resulting recommendations were what the group was able to reach a consensus on. The final product was the result of extensive discussion and compromise. It would not be possible, I don’t believe, to have such a large group of experts agree unconditionally about all aspects of opioid treatment.

**Mr. Adler:** A particularly complex component of the guidelines involves the recommendations for urine drug testing and other monitoring strategies. The guidelines appropriately make the point that “interpretation of urine drug screens is a challenge” and that “clinicians should consider a differential diagnosis for abnormal urine drug screen results.” Although best practices suggest that the overwhelming need remains for clinicians to add urine drug monitoring to their monitoring protocols, there remains no clear criterion on what should be tested, how often, and exactly what course of action should be taken with the results. As an advocate for patients, I am very sensitive to the harm that can arise from a misinterpreted drug test. Although I believe that most patients, in most clinical situations, should be monitored with urine drug testing, there continues to be an evolution with regard to the interpretation of the results. Large-scale urine drug testing has led to the discovery of complex metabolitic pathways, limits to cutoff values, and the presence of manufacturing contaminants. A misinterpreted test could result in severe harm by interruptions in otherwise appropriate care for compliant patients. Looking back, I would have preferred greater awareness of the potential harms associated with misinterpreted urine drug tests, in addition to the significant benefits urine drug testing can provide.
enough evidence. Dr. Ballantyne: I think the positive feedback is that the guidelines were a really comprehensive attempt to look at the literature—as comprehensive as they could be—and although they didn’t provide the evidence we needed, they did provide an indication as to where we need to go. The evidence wasn’t there, but it pointed the way to what does need to be done.

Dr. Passik: I hear negative feedback about the lack of specific detail in risk management. Positive feedback is usually from those who appreciate the bringing together of the database.

Dr. Fine: I have not received any frankly negative feedback, which has truly surprised me. What I really want to know is what the outcomes are in patients treated by clinicians who adhere to the guidelines’ recommendations. As much as it feels good to know that the guidelines have been a welcome addition to pain literature, and the effort of the committee has been appreciated, the only way to assess the value of the guidelines or their consequences is if they have led to positive, health-related outcomes in patients living with chronic pain ... and that information is not immediately available.

Dr. Fishbain: I have not heard any negatives. Again, I think the guidelines were very complete.

Mr. Adler: The most common positive feedback is that the guidelines have served as a thoughtful and useful tool in clinical practice. The majority of stakeholders involved in the care of patients in pain have adopted these guidelines. In many ways, this is remarkable given the controversial subject of providing opioids in noncancer pain. By basing the guidelines on the best evidence available, there has been limited negative feedback. Additionally, the guidelines have built-in flexibility as new evidence emerges.

Dr. Ballantyne: One negative comment I hear is that the guidelines are written by committee—that is, they are consensus guidelines—they don’t offer firm enough guidance. There was a great effort made to include varying perspectives, which is how the committee members were selected. That is both good and bad. The experts had diverse opinions, so ultimately many on the panel were not quite satisfied with the recommendations. That is, of course, a general criticism of consensus guidelines, especially if there is not enough evidence.

Dr. Chou: As I said before, some negative feedback is that the guidelines are “too much” for primary care clinicians. But I don’t think asking clinicians to provide safe care and understanding how to use these medications is “too much.” We also get the opposite negative feedback stating that the guidelines don’t go far enough in discouraging opioid use. But as I said, the guidelines are very clear about the need to perform risk assessment, that opioids aren’t always appropriate, and that there are circumstances in which opioids should be discontinued. In my opinion, clinicians following the recommendations in the guidelines will make more informed and safer prescribing decisions, and that’s an improvement. And in my opinion, there are low-risk patients in whom a trial of opioids is indicated—I just don’t agree with people who say no opioids ever for chronic noncancer pain. For example, I think it would be inappropriate to deny a trial of opioids to a 75-year-old patient with no personal or family history of substance abuse who has severe hip osteoarthritis and either can’t tolerate nonsteroidal anti-inflammatory drugs or hasn’t responded well to them.

Another problem, not with the guidelines per se but with how we deal with chronic pain in general, is that we need to start thinking about this from a systems perspective, not just as an issue of whether to use opioids or not. We know that psychosocial factors have a major influence on chronic pain and we need to make alternatives to opioids—like physical therapy, cognitive-behavioral therapy, and interdisciplinary rehabilitation—available as options. We also need to provide clinicians and patients with the resources so that patients can be withdrawn from opioids or treated for addiction when it’s needed. Just taking away or severely restricting opioids isn’t a particularly effective way of dealing with what is really a societal problem of chronic pain.

Dr. Fanciullo: The most positive feedback has to do with the high quality of the process of guideline creation. We all have Roger Chou to thank for that. Negative feedback has occurred as the entire medical community may have become or is becoming more conservative with regard to opioid use. The appreciation of the dramatic nature of the public health issue regarding addiction, diversion, abuse, and misuse, and the harm these drugs may be causing may have precipitated criticism from individuals who felt the guidelines may not have gone far enough in the area of risk stratification and monitoring. If the guideline process began again today, I think we would have different and likely more “conservative” or restrictive recommendations. But for the 2008-2009 period during which these guidelines were created, I believe they were “right on.”